K073230

ERA 300 Pacing System Analyzer
Additional Battery Supplier
Special 510(k) Premarket Notification

1. 510(K) SUMMARY

Name and Address of Sponsor:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

DEC 2 0 2007

Establishment Registration Number: 1028232

Device Name:

Proprietary Name:	ERA 300 Dual Chamber Pacing System Analyzer
Classification:	Class II/III
Classification Name:	External Pacemaker Pulse Generator (21 CFR 870.3600) Pacemaker Electrode Function Tester (21 CFR 870.3630) Pacemaker Generator Function Analyzer (21 CFR 870.3720)
Product Code:	DTA, DTC, DTE

General Description:

The ERA 300 is a portable, dual chamber pacing system analyzer designed to test the electrical performance of the pulse generator and the pacing lead system or operate as a temporary external pulse generator at the time of pacemaker implantation and during invasive pacemaker troubleshooting or evaluation procedures. The ERA 300 utilizes a touch-proof configuration to help prevent hazardous connection between patients and electrical power sources.

Device Modifications:

The 8 Volt battery currently supplied with the ERA 300 Pacing System Analyzer (PSA) is manufactured by Panasonic. However, in the future this supplier will no longer manufacture this battery model. Therefore, an additional supplier for the 8 Volt battery supplied with the ERA 300 PSA was identified, **pbq**. The **pbq** manufactured battery meets the same internal BIOTRONIK specifications including purchasing specifications, incoming inspection, and performance specifications.

Predicate Devices:

BIOTRONIK proposes the following predicate device for the battery modification to the ERA 300 Pacing System Analyzer:

- BIOTRONIK's ERA 300 Pacing System Analyzer (#K964190, cleared 07-10-97 and #K033613, cleared on 12-08-03)

Indications for Use:

The ERA 300 is intended for use during invasive pacemaker procedures in the following activities:

- **Temporary External Pacing**
  Provides temporary stimulation under DDD, DDI, DOO, VVI, VDD, VOO, AAI, or AOO modalities during implantable pacemaker procedures or physician evaluations.
- **Lead Threshold Determination**
  Determines in situ lead characteristics of impedance, capture threshold, P/R wave amplitude and P/R wave slew rate. Determines the in vivo retrograde conduction time.
- **Pacemaker Function Test**
  Tests and analyzes the in vitro operation of external or implantable pulse generators. Determines the following parameters: pulse amplitude and width, sensitivity, refractory period, A/V delay, and rate/interval.

Name and Address of Manufacturer:

BIOTRONIK GmbH & Co. KG
Woermannkehre 1,
12359 Berlin, Germany
011-49-30-689-05-1210

Manufacturer's Registration Number:

9610139

Contact Person(s) and Phone Number:

Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
Phone (888) 345-0374
Fax (503) 635-9936
jon.brumbaugh@biotronik.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2007

Biotronik, Inc.
c/o Mr. Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
6024 Jean Road
Lake Oswego, OR 97035

Re: K073230
Trade/Device Name: ERA 300 Pacing System Analyzer
Regulation Number: 21 CFR 870.3600
Regulation Name: External Pacemaker Pulse Generator
Regulatory Class: Class III (three)
Product Code: DTA, DTC, DTE
Dated: November 14, 2007
Received: November 15, 2007

Dear Mr. Brumbaugh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073230

Device Name:
ERA 300 Pacing System Analyzer

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Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K073230